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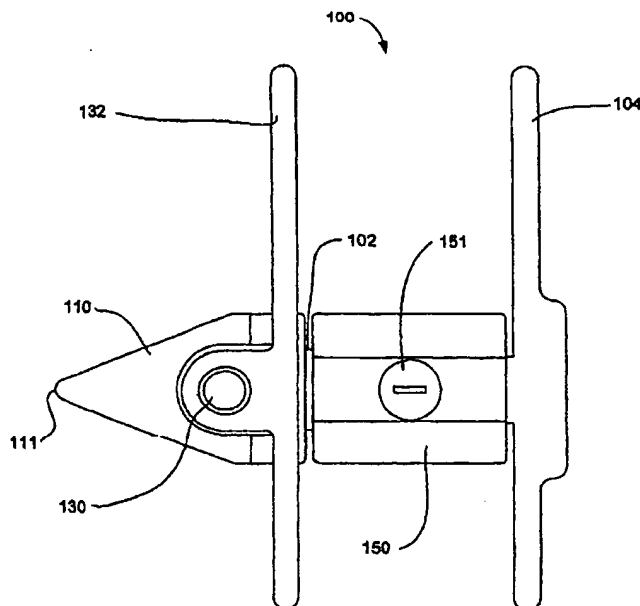
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(54) Title: INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER



(57) Abstract: The present invention is an interspinous process implant with a selectably expandable spacer that can be placed between adjacent spinous processes.

**INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A
SELECTABLY EXPANDABLE SPACER**

CLAIM OF PRIORITY

[0001] This application claims priority to U.S. Provisional Application No. 60/421,921, filed on October 29, 2002, entitled "INTERSPINOUS PROCESS APPARATUS AND METHOD WITH A SELECTABLY EXPANDABLE SPACER" (Attorney Docket No. KLYC-01056USC), which is incorporated herein by reference.

CROSS-REFERENCE TO RELATED APPLICATIONS AND PATENTS

[0002] This application is related to U.S. Patent Application Serial No. 10/037,236, filed on November 9, 2001, which is related to U.S. Patent Application Serial No. 09/799,215, filed on March 5, 2001, which is a related to U.S. Patent Application Serial No. 09/179,570, filed on October 27, 1998, now U.S. Patent 6,048,342, which is related to U.S. Patent Application Serial No. 09/175,645, filed on October 20, 1998, now U.S. Patent 6,068,630. This application is also related to U.S. Patent No. 5,836,948, issued November 17, 1998 and U.S. Patent No. 5,860,977, issued January 19, 1999. All of the above are incorporated herein by reference.

FIELD OF THE INVENTION

[0003] This invention relates to an apparatus and method for adjustably distracting the spinous process of adjacent vertebrae.

BACKGROUND OF THE INVENTION

[0004] The spinal column is a bio-mechanical structure composed primarily of ligaments, muscles, vertebrae and intervertebral disks. The bio-

mechanical functions of the spine include: (1) support of the body, which involves the transfer of the weight and the bending movements of the head, trunk, and arms to the pelvis and legs, (2) complex physiological motion between these parts, and (3) protection of the spinal cord and the nerve roots.

[0005] As the population ages, it is anticipated that there will be an increase in adverse spinal conditions characteristic in older persons. For example, with aging comes an increase in spinal stenosis (including, but not limited to, central canal and lateral stenosis), the thickening of the bones that make up the spinal column, and facet antroopathy. Spinal stenosis is characterized by a reduction in the available space for the passage of blood vessels and nerves. Pain associated with such stenosis can be relieved by medication and/or surgery. Of course, it is desirable to eliminate the need for major surgery for all individuals, and, in particular, for the elderly.

[0006] In addition, there are a variety of other ailments that can cause back pain in patients of all ages. For these ailments it is also desirable to eliminate such pain without major surgery.

[0007] Accordingly, there is a need for a method for alleviating such conditions that is minimally invasive, can be tolerated by patients of all ages (in particular, the elderly), can be performed on an out-patient basis, and allows adjustments both during and after surgery to minimize patient discomfort. There is a further need for an apparatus with which to apply the method.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] **Figs. 1a-1f.** Fig. 1a is a front plan view of one embodiment of an apparatus with a selectably expandable spacer; Fig. 1b is a left side view of the apparatus of Fig. 1a; Fig. 1c is a front plan view of the apparatus of Fig. 1a including a selectably expandable spacer, a main body and a first wing; Fig. 1d is a left side view of the second wing of the apparatus of Fig. 1a; Fig. 1e is a front plan view of the second wing of the apparatus of Fig. 1a; Fig. 1f is an end view of the selectably expandable spacer of the apparatus of Fig. 1a.

[0009] **Figs. 2a and 2b.** Fig. 2a is a right side view of an embodiment of the selectably adjustable spacer in an unexpanded position. Fig. 2b is a right side view of an embodiment of the selectably adjustable spacer in a fully expanded position.

[0010] **Figs. 3a and 3b.** Fig. 3a is a right side cross-sectional view of an embodiment of the selectably adjustable spacer in an unexpanded position. Fig. 3b is a left side cross-sectional view of an embodiment of the selectably adjustable spacer in a fully expanded position.

[0011] **Fig. 4** is a front side view of an embodiment of the selectably adjustable spacer.

[0012] **Fig. 5a** is a perspective view of an embodiment of the selectably adjustable spacer. **Fig. 5b** is a back view of another embodiment of the spacer similar to that shown in Fig. 5a with a mechanism for allowing the spacer to expand.

[0013] **Figs. 6a and 6b.** Fig. 6a is a right side view of an alternative embodiment of the selectably expandable spacer with a jack expansion mechanism in an unexpanded position. Fig. 6b is a right side view of an alternative embodiment of the selectably expandable spacer with a jack expansion mechanism in a fully expanded position.

[0014] **Fig. 7** is a block diagram demonstrating the steps for performing the method.

Detailed Description of the Preferred Embodiment

[0015] The following description is presented to enable any person skilled in the art to make and use the invention. Various modifications to the embodiments described will be readily apparent to those skilled in the art, and the principles defined herein can be applied to other embodiments and applications without departing from the spirit and scope of the present invention as defined by the appended claims. Thus, the present invention is not intended to be limited to the embodiments shown, but is to be accorded the widest scope consistent with the principles and features disclosed herein. To the extent

necessary to achieve a complete understanding of the invention disclosed, the specification and drawings of all patents and patent applications cited in this application are incorporated herein by reference.

[0016] Figs. 1a-1f illustrate an embodiment of an apparatus, or implant 100, suitable for use with the method of this invention. The implant 100 includes a first wing 104, a selectably expandable spacer 150 and a lead-in tissue expander or distraction guide 110. The implant further includes, as required, a second wing 132. As can be seen in Fig. 1a, a shaft 102 extends from the first wing 104 and is the body that connects the first wing to the distraction guide 110. Also, as can be seen in Figs. 1a and 1b, the guide 110 in this particular embodiment is pointed in order to allow the implant to be inserted between, and, if necessary, to distract adjacent spinous processes. In this particular embodiment, the guide 110 has a wedge-shaped cross-section, expanding from the distal end 111 to the area where the second wing 132 can be optionally secured to the guide. Figs. 1b and 1c illustrate an embodiment of the implant 100 with only a first wing 104.

[0017] As required, implant 100 can include a second wing 132 which fits over the guide 110 and is secured by a bolt 130 placed through aperture 134 of the second wing 132 to the threaded bore 112 located in the guide 110. As implanted, the first wing 104 is located adjacent to first sides of the spinous processes and the second wing 132 is located adjacent to second sides of the same spinous processes.

[0018] The spacer 150 is rotatably mounted about a shaft 102. The spacer 150 is positioned between the first wing 104 and the guide 110. The tissue expander 110 guides the spacer 150 into position between the spinous process of adjacent vertebrae. The spacer 150 includes a slotted sphere 151 that when rotated is positioned along a lead-screw, expanding or collapsing the spacer.

[0019] Figs. 1f, 2a-b, 3a-b, and 5 illustrate a preferred embodiment of the spacer 150 wherein the shape of the spacer 150 is oval or elliptical in cross-section, although it can alternatively be circular or ovoid or race-track shaped in

cross-section. It is to be understood that the spacer 150 can have other shapes as described throughout the specification and be within the spirit and scope of the invention. In a preferred embodiment, the spacer 150 includes a bore 152 extending the length of the spacer 150. The bore 152 of the spacer 150 is received over the shaft 102 of the implant 100 so that, as described above, the spacer can be rotated about the shaft 102. In these embodiments, the spacer 150 can have minor and major dimensions as follows:

Minor Dimension (116a)	Major Dimension (116 b)
6 mm	10 mm
8 mm	10.75 mm
12 mm	14 mm
6 mm	12.5 mm
8 mm	12.5 mm
10 mm	12.5 mm

[0020] One advantage of the use of the spacer 150, as depicted in the embodiment of Fig. 1a, is that the spacer 150 can be partially rotated and repositioned with respect to the first wing 104 in order to optimize positioning of the implant 100 between spinous processes. It is to be understood that the cortical bone or the outer bone of the spinous processes is stronger at an anterior position adjacent to the vertebral bodies of the vertebra than at a posterior position distally located from the vertebral bodies. Also, biomechanically for load bearing, it is advantageous for the spacer 150 to be close to the vertebral bodies. In order to facilitate this and to accommodate the anatomical form of the bone structures, as the implant is inserted between the spinous processes and/or urged toward the vertebral bodies, the spacer 150 rotates relative to the wings, such as wing 104, so that the spacer 150 is optimally positioned between the spinous processes, and the wing 104 is optimally positioned relative to the spinous processes.

[0021] In another embodiment, the spacer 150 has a cross-section with a major dimension and a minor dimension, wherein the major dimension is greater than the minor dimension, and, for example, less than about two times

the minor dimension. It is to be understood that the spacer 150 can be fabricated from somewhat flexible and/or deflectable material.

[0022] In this embodiment the spacer is made out of a polymer, more specifically, the polymer is a thermoplastic. Still more specifically, the polymer is a polyketone known as polyetheretherketone (PEEK™). Still more specifically, the material is PEEK 450G, which is an unfilled PEEK approved for medical implantation available from Victrex of Lancashire, Great Britain. (Victrex is located at www.matweb.com or see Boedeker www.boedeker.com). Other sources of this material include Gharda located in Panoli, India (www.ghardapolymers.com).

[0023] The spacer 150 can be formed by extrusion, injection, compression molding and/or machining techniques. This material has appropriate physical and mechanical properties and is suitable for carrying and spreading the physical load between the spinous process. For example, in this embodiment, the PEEK has the following approximate properties:

Density	1.3 g/cc
Rockwell M	99
Rockwell R	126
Tensile Strength	97 MPa
Modulus of Elasticity	3.5 GPa
Flexural Modulus	4.1 GPa

[0024] It should be noted that the material selected may also be filled. For example, other grades of PEEK are also available and contemplated, such as 30% glass-filled or 30% carbon-filled, provided such materials are cleared for use in implantable devices by the FDA, or other regulatory body. Glass-filled PEEK reduces the expansion rate and increases the flexural modulus of PEEK relative to that which is unfilled. The resulting product is known to be ideal for improved strength, stiffness, or stability. Carbon-filled PEEK is known to enhance the compressive strength and stiffness of PEEK and lower its expansion rate. Carbon-filled PEEK offers wear resistance and load carrying capability.

[0025] In this embodiment, as described above, the spacer 150 is manufactured from polyetheretherketone (PEEK™), available from Victrex. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polycondensate materials that resist fatigue, have good memory, are flexible, and/or deflectable, have very low moisture absorption, and good wear and/or abrasion resistance, can be used without departing from the scope of the invention. The spacer can also be comprised of polyetherketoneketone (PEKK).

[0026] Other materials that can be used include polyetherketone (PEK), polyetherketoneetherketoneketone (PEKEKK), and polyetheretherketoneketone (PEEKK), and generally a polyaryletheretherketone. Further other polyketones can be used as well as other thermoplastics. The spacer can also be made of titanium.

[0027] Reference to appropriate polymers that can be used in the spacer can be made to the following documents, all of which are incorporated herein by reference. These documents include: PCT Publication WO 02/02158 A1, dated January 10, 2002, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270 A1, dated January 3, 2002, entitled "Bio-Compatible Polymeric Materials."

[0028] Other materials such as Bionate®, polycarbonate urethane, available from the Polymer Technology Group, Berkeley, California, may also be appropriate because of the good oxidative stability, biocompatibility, mechanical strength and abrasion resistance. Other thermoplastic materials and other high molecular weight polymers can be used.

[0029] A preferred embodiment of the spacer is illustrated in Figs. 2a-5. In Figs. 2a and 2b the spacer 150 includes a first portion 260 pivotably or rotatably coupled with a second portion 261 by a hinge (shown in Fig. 4). Both the first portion 260 and the second portion 261 have tapered distal ends that form an acute angle between the two portions. Fig. 2a illustrates the acute angle 265a formed when the spacer 150 is in the unexpanded position. The first

portion 260 has a bore 252 through which the shaft 102, shown in Fig. 1a, is received, connecting the first wing 104 with the guide 110 and connecting the spacer 150 with the implant 100. The bore 252 allows the spacer 150 to partially rotate about the shaft 102. The second portion 261 of the spacer 150 also has a bore that is located behind and aligned with the bore 252, shown in Fig. 2a. This bore is also received on the shaft 102 so that both the first and second portions of the spacer 150 can rotate about the shaft 102. A threaded screw 253 protrudes through the angle 265a formed by the tapered distal ends of the portions. The end of the threaded screw 253 also has a bore that aligns with the bores of the first and second portions of the spacer 150 and is received on the shaft 102 and can rotate about the shaft 102. A slotted sphere 151 is connected with the distal end of screw 253. In the least expanded position, the slotted sphere 151 is at the farthest point of travel away from the proximal end of the screw 253 Fig. 2a.

[0030] Fig. 2b illustrates the acute angle 265b formed when the spacer 150 is in the fully expanded position. The slotted sphere 151 is rotated such that the sphere travels toward the proximal end of the threaded screw 253. As the slotted sphere 151 travels toward the proximal end of the screw 253, the sphere 151 forces the tapered distal ends of the portions 260, 261 apart. As the distal ends of the portions are forced apart, the first portion 260 and the second portion 261 rotate in opposite directions about a common hinge 463 (shown in Fig. 4), sliding along the contact surface 262. As the acute angle formed by the distal ends of the portions increases, the height of the spacer 150 expands.

[0031] Figs. 3a and 3b illustrate in cross-section the preferred embodiment of the selectably expandable spacer described in reference to Figs. 2a and 2b. The slotted sphere 151 has a threaded cavity for receiving the threaded screw 253 when the sphere 151 is rotated. The slotted sphere 151 travels the distance 351c such that the distal end of the screw 253 moves from position 351a to position 351b along the threaded cavity of the sphere when adjusted from an unexpanded to a fully expanded position. When rotated in the opposite direction, the slotted sphere 151 moves away from the proximal end of

the screw 253, collapsing the spacer 150. Fig. 3b illustrates the spacer 150 in a fully expanded position with the distal end of the screw 253 at the maximum position 351b in the threaded cavity of the slotted sphere 151. It is to be understood that portions 260, 261 of the spacer 150 can be biased to the closed position shown in Fig. 3a. The biasing can be accomplished by a spring that is coiled in or about the bore of the spacer that receives the shaft 102. Such a spring would be connected to both of the portions 260, 261 of the spacer 150.

[0032] The first and second portions of the spacer 150 in combination, can have a cross-section that is elliptical, oval, ovoid, football-shaped, circular-shaped, rectangular with rounded ends (where the cross-section has two somewhat flattened surfaces and two rounded surfaces similar to the effect of a flattened ellipse) or race-track shaped. Further, the first and second portions can have different cross-sectional shapes relative to each other. At least the minor dimension (the height) of the spacer is between 6 mm and 14 mm. Typically, the minor outer dimension is one of 6 mm, 8 mm, 10 mm, 12 mm, and 14 mm. The different sizes and selectable expandability enable the spacer to accommodate different sized patients.

[0033] As discussed above, the spacer 150 and its components, including either the first or second portions, or both, can be made of a number of materials. Suitable materials can include polymers, such as, for example, polyetheretherketone (PEEK™), as well as other materials described above, including titanium. Such materials can be deflectable and flexible depending on the configuration of the spacer 150.

[0034] Further, the deflectable or flexible material can have a graduated stiffness to help gradually distribute the load when the spinous processes place a force upon the exterior surface of the spacer. This can be accomplished by forming multiple layers of the deflectable or flexible material with decreasing stiffness or hardness from the center of the spacer outwardly. Alternatively, the material can have a higher stiffness or hardness in the center of the inner spacer.

[0035] Referring to Fig. 4, the slotted sphere 151 is positioned approximately equidistant from a first and second ends of the spacer 150,

distributing the parting force of the sphere 151 so as not to create disproportionate stress on either side of the spacer 150.

[0036] A hinge 463 couples a first portion 260 with a second portion 261, such that the two portions pivot about the hinge 463, expanding or collapsing the gap 465.

[0037] A perspective view is provided in Fig. 5a, showing the clam-shape of the preferred embodiment of the spacer 150. The implant 100 is positioned between the adjacent vertebrae so as to permit access to the slot 554 from a posterior direction both during and after surgery. Post-surgery adjustment is made using a cannula inserted through the patient's back. Convenient access to the slot 554 is important for reducing patient discomfort and procedure complication.

[0038] The bore 252 provides a sleeve for the shaft 102, and also limits the rotation of the spacer 150 about the shaft 102. Limiting the rotation of the spacer 150 can be accomplished, for example, by providing a slot 255 in the bore 252 and a key on the shaft 102, or vice-versa. One of skill in the art can appreciate that different mechanisms and geometries can be used to limit spacer rotation. Reference is also made to a copending U.S. patent application entitled "Spinal Implants, Insertion Instruments, and Methods of Use," filed on March 5, 2001, as U.S. Patent Application Serial No. 09/799,470 (KLYC-1027US1), which is incorporated herein by reference and which discloses an implant which has a spacer with a slot and an implantation tool that includes a probe that engages the slot in order to position the spacer relative to the implantation tool for desirable initial positioning of the space relative to the spinous processes. Such a mechanism can be used by itself or in addition to the above discussed keyway and key for purposes of positioning the sphere 151 so that the height of the spacer 150 can be selectively adjusted during the initial surgical procedure or, thereafter, should such adjustment be desirable due, for example, to the need for more distraction between the spinous processes.

[0039] Fig. 5b depicts the back of another embodiment of the spacer 150 of the implant 100 of the invention. Fig. 5b is similar to a back view of the

embodiment depicted in Fig. 4. In Fig. 5b, the spacer 150 includes the first and second portions 260, 261, respectively. The first portion includes a bore 252 that receives the shaft 102 and the second portion includes bore 254 that also receives the shaft 102. In addition, the screw 253 is shown with a portion of the sphere 151 that is used to adjust the height of the spacer 150. The screw 253 includes a bore 257 that also receives the shaft 102. Thus, the first and second portions of the spacer and the screw are rotatable about the shaft.

[0040] One of skill in the art can also appreciate the different expansion mechanisms that can be employed to expand the spacer 150. For example, an expansion mechanism could include: pistons, ratchets, cams, jacks, or other machines. Figs. 6a and 6b illustrate one alternative embodiment in which a jack 651 is used to expand the spacer 150. The jack 651 is expanded or collapsed by rotating a slotted screw 653, thereby increasing or decreasing the gap 665. Fig. 6a shows the spacer 150 in an unexpanded position with a narrow gap 665a.

[0041] Fig. 6b illustrates another alternative embodiment utilizing a jack, whereby the hinge 462 can allow for translation of the first and second portions in the y-direction as well as for rotation about the hinge 462, thereby reducing the stresses on the side of the jack closest to the hinge caused by uneven compression when the gap 665b expands. For the embodiment in Figs. 6a and 6b any of the above devices for allowing the first portion of the spacer to move relative to the second portion of the spacer can be employed, as well as other known methods, and be within the spirit and scope of the invention.

[0042] The preferred method for inserting the implant between adjacent vertebrae is block-diagramed in Fig. 7. The method requires that the spine be surgically exposed. The implant is then inserted between the spinous processes, with the wedge shape of the guide forcing tissue apart to create room for the implant. Once the implant is in place, with the spacer between adjacent vertebrae, the profile of the implant is adjusted by expanding or collapsing the spacer using a tool for operating the expansion mechanism. The wound is then closed.

[0043] The implant can subsequently be readjusted with the insertion of a cannula through which a tool is inserted for operating the expansion mechanism.

[0044] The embodiment of this apparatus as well as the several other apparatuses described herein, act to limit extension (backward bending) of the spine. These apparatuses, however, do not inhibit the flexion (forward bending) of the spinal column.

[0045] The foregoing description of embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to the practitioner skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention and the various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalence.

What is claimed:

- 1 1. An implant adapted to be placed between spinous processes
2 comprising:
3 a spacer that is adapted to fit between spinous processes; and
4 a means for adjusting the height of the spacer in order to adjust
5 the spacing between the spinous processes.
- 1 2. The implant of claim 1 wherein the spacer has an elliptical shape
2 in at least one dimension wherein a height of the spacer in that dimension is less
3 than a length of the spacer in another dimension.
- 1 3. The implant of claim 1 wherein the spacer has a first portion and
2 a second portion which are movable relative to each other.
- 1 4. The implant of claim 1 wherein the adjusting means includes a
2 first portion and a second portion of the spacer connected by a hinge.
- 1 5. The implant of claim 1 wherein the adjusting means includes the
2 spacer of the implant further comprises a slotted sphere.
- 1 6. The implant of claim 5 wherein the slotted sphere engages the
2 first and second portion of the spacer to maintain the profile height.
- 1 7. The implant of claim 5 wherein the slotted sphere engages a
2 screw extending from between first and second portion of the spacer to maintain
3 the profile height.
- 1 8. The implant of claim 3 wherein the first portion and the second
2 portion each have a curved surface on a first side and a height adjuster
3 contacting surface on a second side opposite the first side.
- 1 9. The implant of claim 1 wherein the adjusting means of the
2 implant further comprises a jack.

1 10. The implant of claim 9 where the said jack is adjustable to a
2 greater profile and a lesser profile by turning a screw in one of a first direction
3 and a second direction.

1 11. An implant adapted to be placed between spinous processes
2 comprising:
3 a body having a shaft extending therefrom;
4 a spacer pivotally mounted on the body, the spacer including a
5 first portion and a second portion; and
6 a mechanism positioned between the first portion and the second
7 portion that can adjust a space between the first and second portion.

1 12. The implant of claim 11 wherein the spacer has an elliptical
2 shape.

1 13. The implant of claim 11 wherein the first portion and the second
2 portion of the spacer are connected proximal to an end thereof by a hinge.

1 14. The implant of claim 11 wherein the mechanism of the implant
2 further comprises a slotted sphere.

1 15. The implant of claim 14 wherein the slotted sphere engages the
2 first and second portion of the spacer to maintain the profile height.

1 16. The implant of claim 14 wherein the slotted sphere engages a
2 screw extending from the hinge between the first and second portion of the
3 spacer to maintain the profile height.

1 17. The implant of claim 11 wherein the first portion and the second
2 portion each have a curved surface on a first side and a height adjuster surface
3 on a second side opposite the first side.

1 18. The implant of claim 11 wherein the mechanism of the implant
2 further comprises a jack.

1 19. The implant of claim 18 wherein the jack engages the first and
2 second portion of the spacer to maintain the profile height.

1 20. The implant of claim 18 wherein the jack is adjustable to a
2 greater profile and a lesser profile by turning a screw in one of a first direction
3 and a second direction.

1 21. An implant adapted to be placed between spinous processes
2 comprising:
3 a body having a shaft extending therefrom;
4 a first wing extending from the shaft and adapted to be placed
5 adjacent a first and a second spinous process;
6 a tissue expander extending from the distal end of the shaft;
7 a spacer that is rotatably mounted to the shaft, the spacer having
8 a first portion and a second portion; and
9 a mechanism that is mounted to the spacer and that can adjust the
10 spacing between the first and second portions of the spacer.

1 22. The implant of claim 21 wherein the spacer is elliptical in shape
2 with the first portion and the second portion divided about a major axis of the
3 elliptical shaped spacer.

1 23. The implant of claim 21 wherein the first portion and the second
2 portion of the spacer are connected by a hinge.

1 24. The implant of claim 21 wherein the mechanism of the implant
2 further comprises a slotted sphere.

1 25. The implant of claim 24 wherein the slotted sphere engages the
2 first and second portion of the spacer to maintain the profile height.

1 26. The implant of claim 24 wherein the slotted sphere engages a
2 screw extending from between the first and second portion of the spacer to
3 maintain the profile height.

1 27. The implant of claim 21 wherein the mechanism of the implant
2 further comprises a jack.

1 28. The implant of claim 27 wherein the jack engages the first and
2 second portion of the spacer to maintain the profile height.

1 29. The implant of claim 27 where the said jack is adjustable to a
2 greater profile and a lesser profile by turning a screw in one of a first direction
3 and a second direction.

1 30. An implant adapted to be placed between spinous processes
2 comprising:

3 a body having a shaft extending therefrom; and
4 a spacer that is rotatably mounted on the shaft,
5 wherein the spacer has an adjustable profile.

1 31. The implant of claim 30 wherein the spacer has an elliptical
2 shape.

1 32. The implant of claim 30 wherein the spacer has a first portion
2 and a second portion.

1 33. The implant of claim 32 wherein the first portion and the second
2 portion of the spacer are connected by a hinge.

1 34. The implant of claim 30 wherein the spacer of the implant
2 further comprises a slotted sphere.

1 35. The implant of claim 34 wherein the slotted sphere engages the
2 first and second portion of the spacer to maintain the profile height.

1 36. The implant of claim 34 wherein the slotted sphere engages a
2 screw to maintain the profile height.

1 37. The implant of claim 32 wherein the first portion and the second
2 portion each have a curved surface on a first side and a height adjuster
3 contacting surface on a second side opposite the first side.

1 38. The implant of claim 30 wherein the spacer of the implant
2 further includes a jack.

1 39. An implant adapted to be placed between spinous processes
2 comprising:
3 a body having a shaft extending therefrom; and
4 a spacer that is rotatably mounted on the shaft;
5 wherein the spacer has a hinged body having a first portion and a
6 second portion; and
7 a device to adjust a space between the first portion and the
8 second portion.

1 40. The implant of claim 39 wherein the device of the implant
2 further comprises a slotted sphere.

1 41. The implant of claim 40 wherein the slotted sphere engages the
2 first and second portion of the spacer to maintain the profile height.

1 42. The implant of claim 39 wherein the device of the implant
2 further comprises a jack.

1 43. A method of implanting a device between an upper and lower
2 spinous process in a spine, the method comprising:

- 3 a. exposing an affected region of the spine posteriorly;
- 4 b. inserting an implant between the spinous processes;
- 5 c. adjusting the profile of the implant; and
- 6 d. closing the wound.

1 44. A method of adjusting an interspinous implant, the method
2 comprising:

- 3 a. accessing the implant with a cannula; and
- 4 b. adjusting a profile of the implant with a tool accessed
- 5 through the cannula.

1 45. A method of adjusting an implanted interspinous implant having
2 a body having a shaft extending therefrom, a spacer pivotally mounted on the
3 body, and a screw for adjusting the space between a first portion and a second
4 portion of the spacer, the method comprising:

- 5 a. accessing the screw of the implanted interspinous implant
- 6 through an incision with a cannula; and
- 7 b. adjusting a profile of the implant with a tool accessed
- 8 through the cannula by turning the screw of the implant in one of a first
- 9 direction or a second direction.

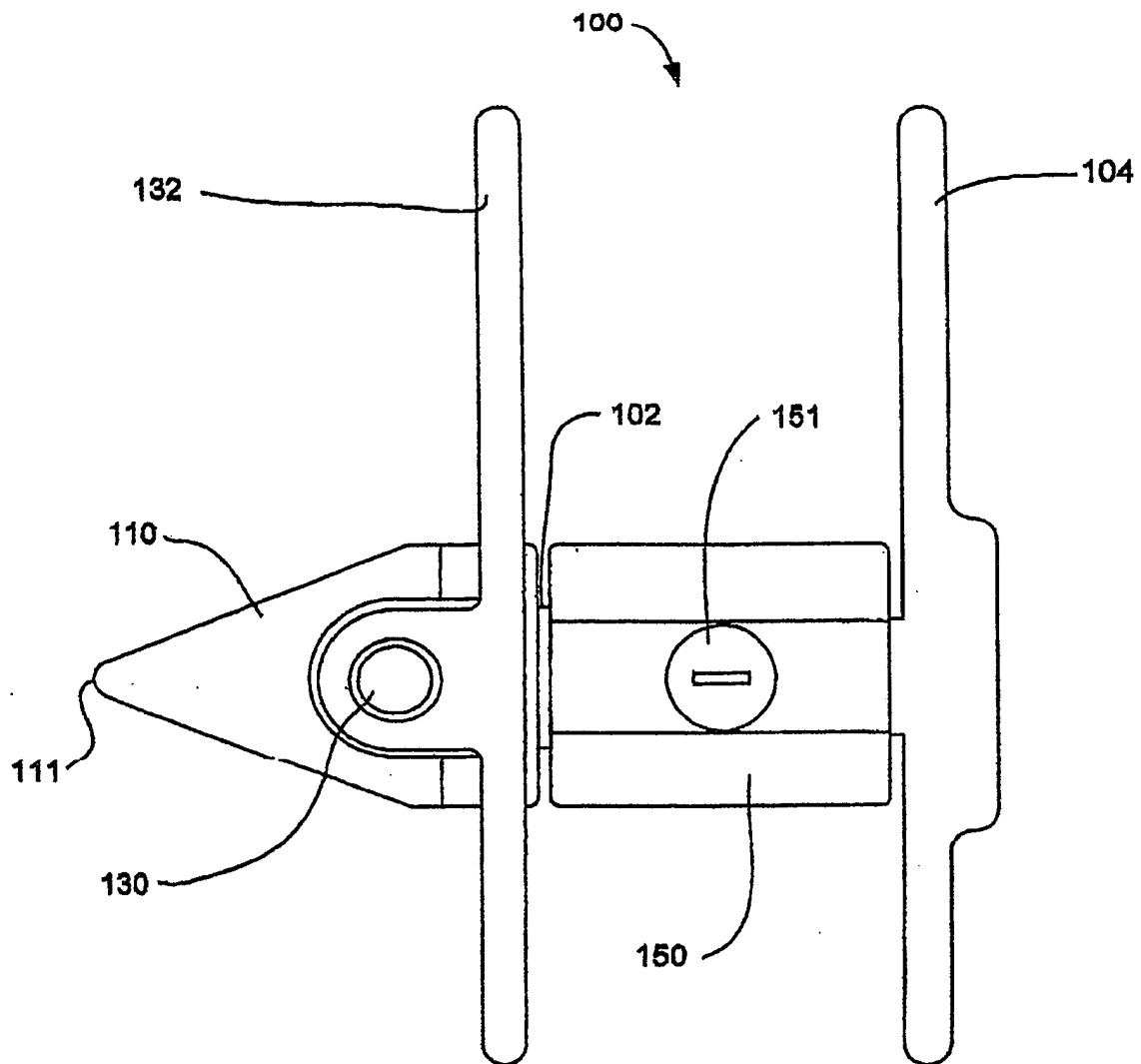


FIG. - 1A

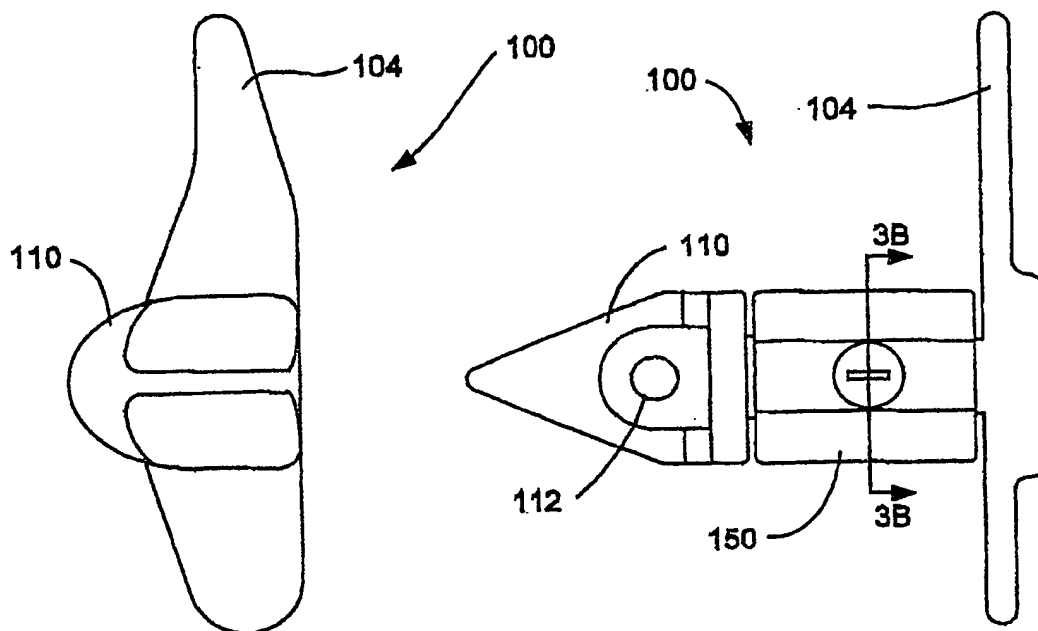


FIG. - 1B

FIG. - 1C

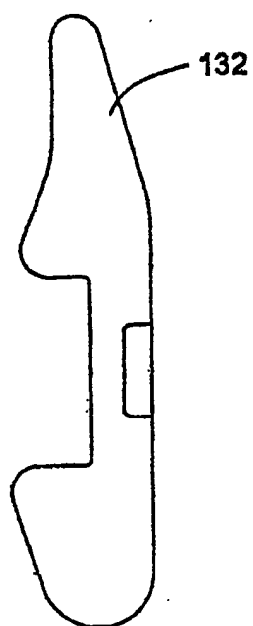


FIG. - 1D

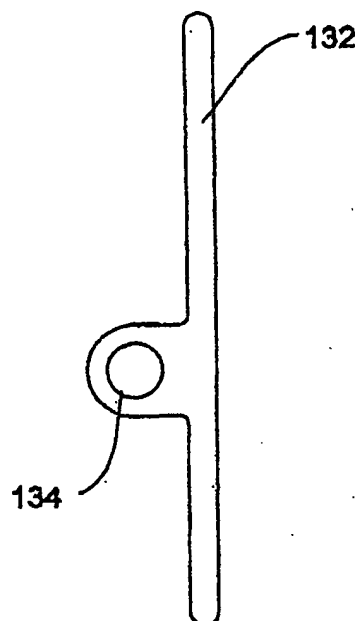


FIG. - 1E

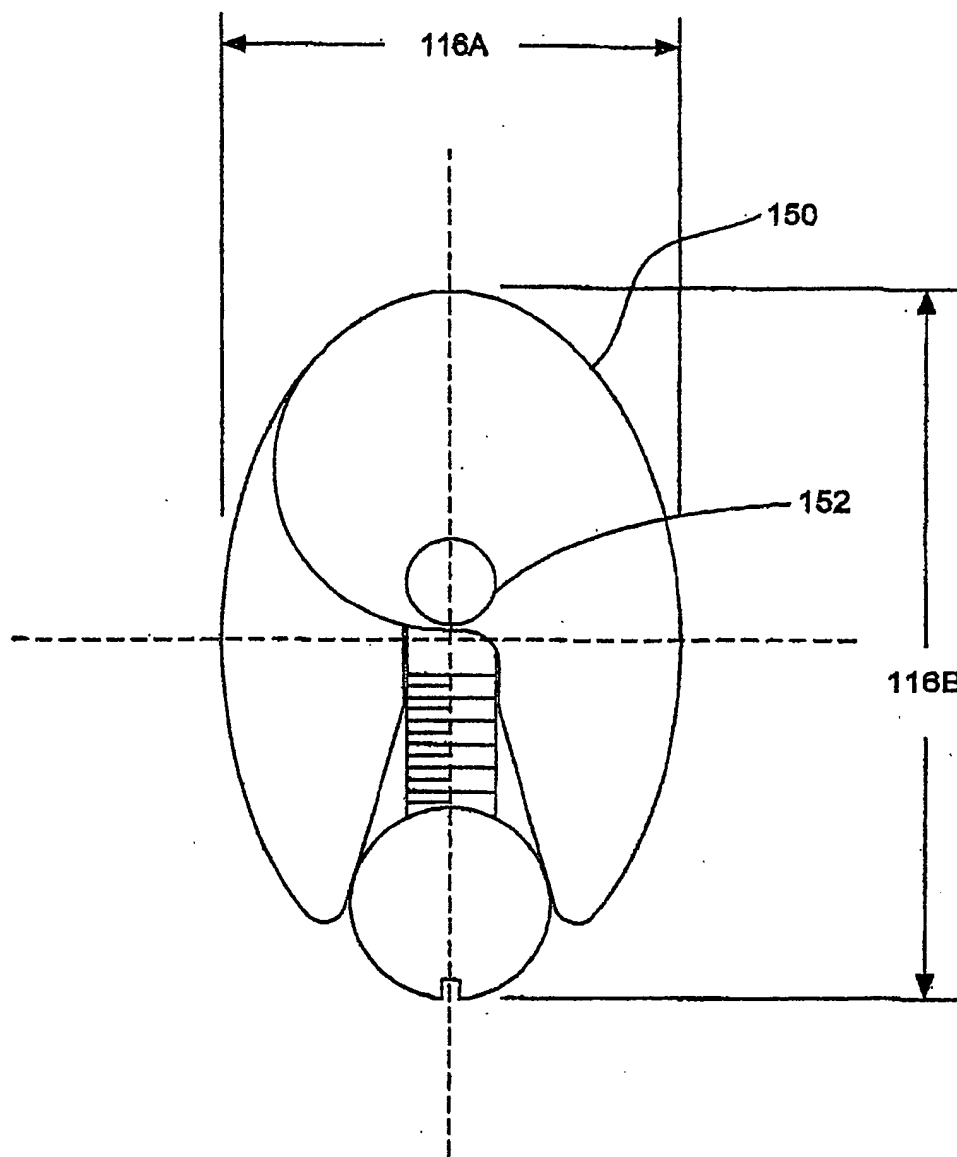


FIG. - 1F

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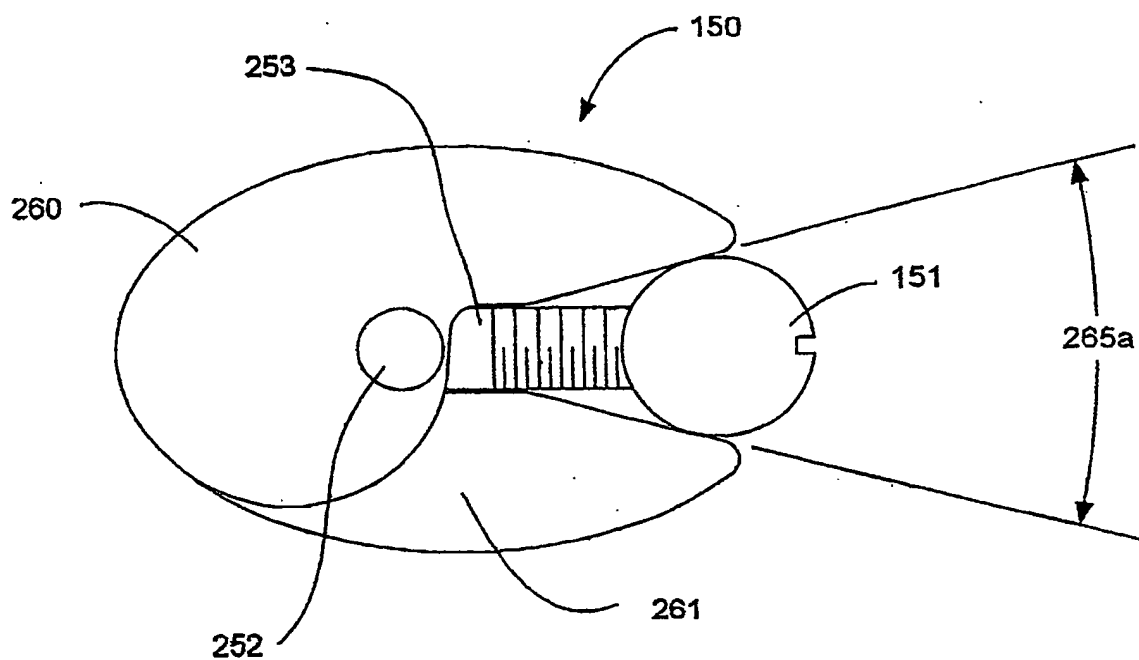


FIG. - 2A

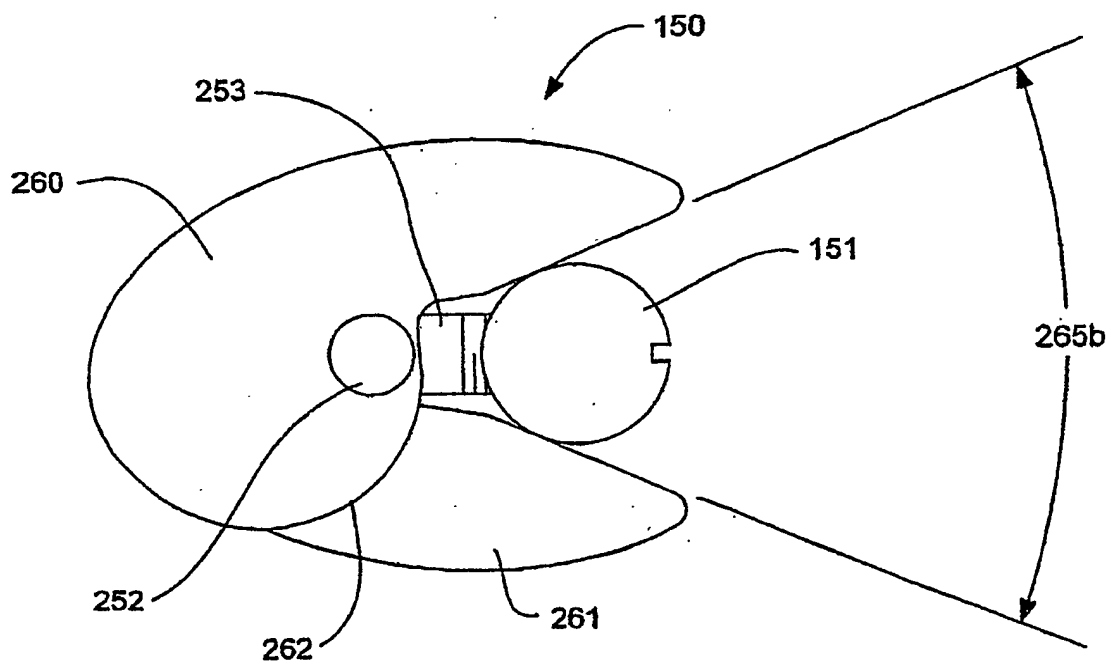


FIG. - 2B

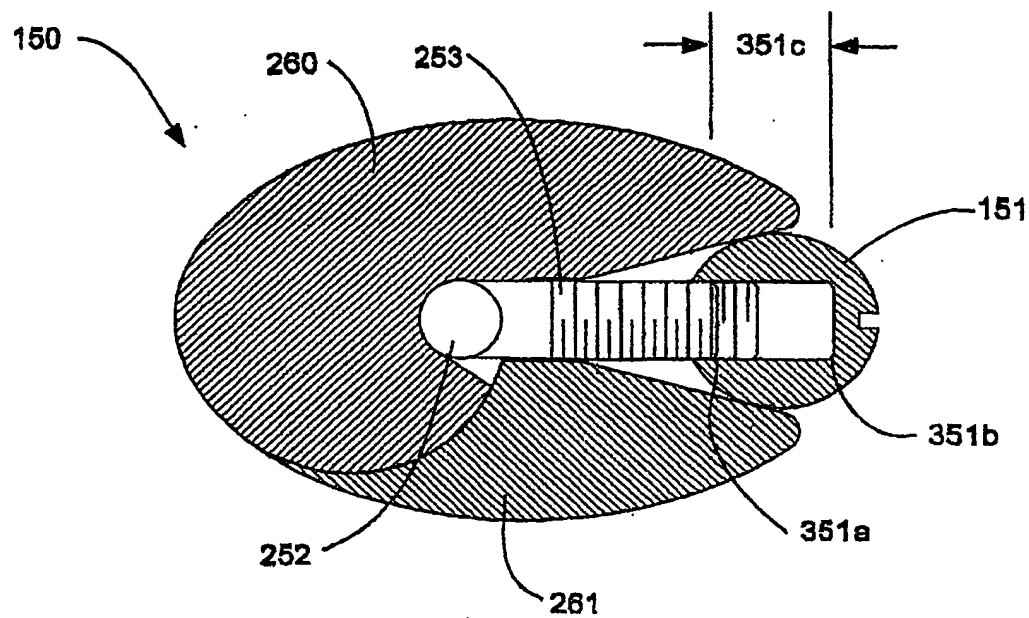


FIG. - 3A

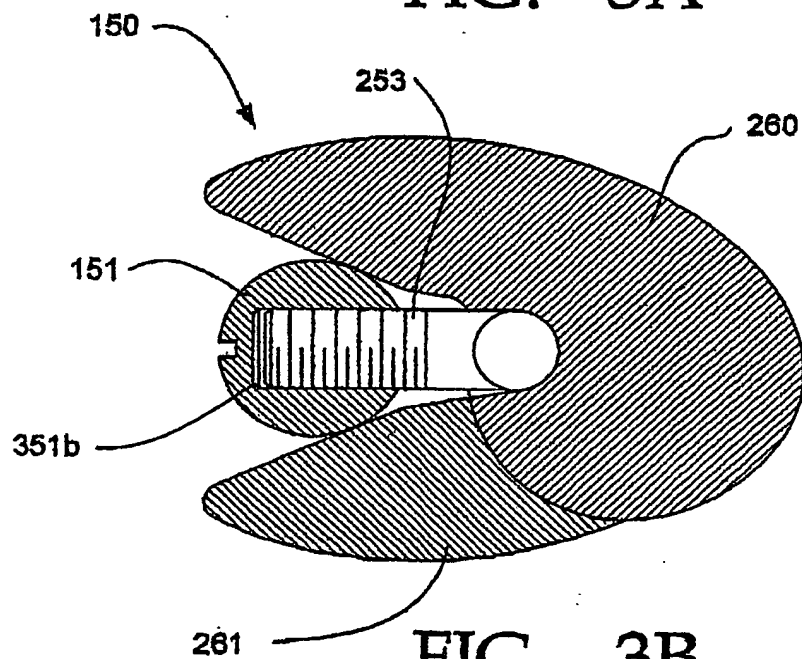


FIG. - 3B

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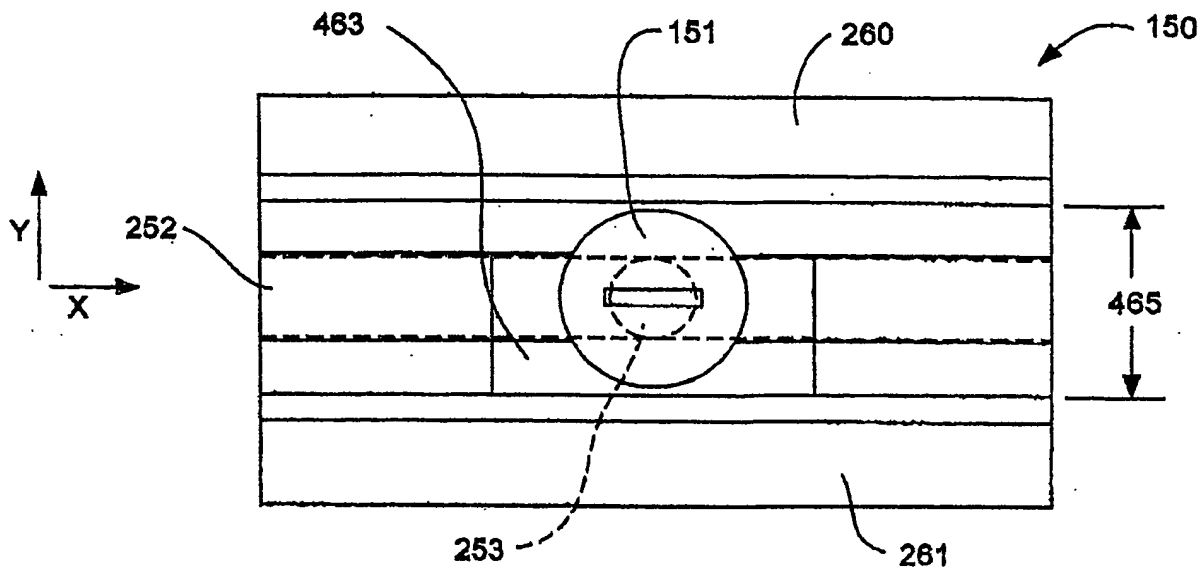


FIG. - 4

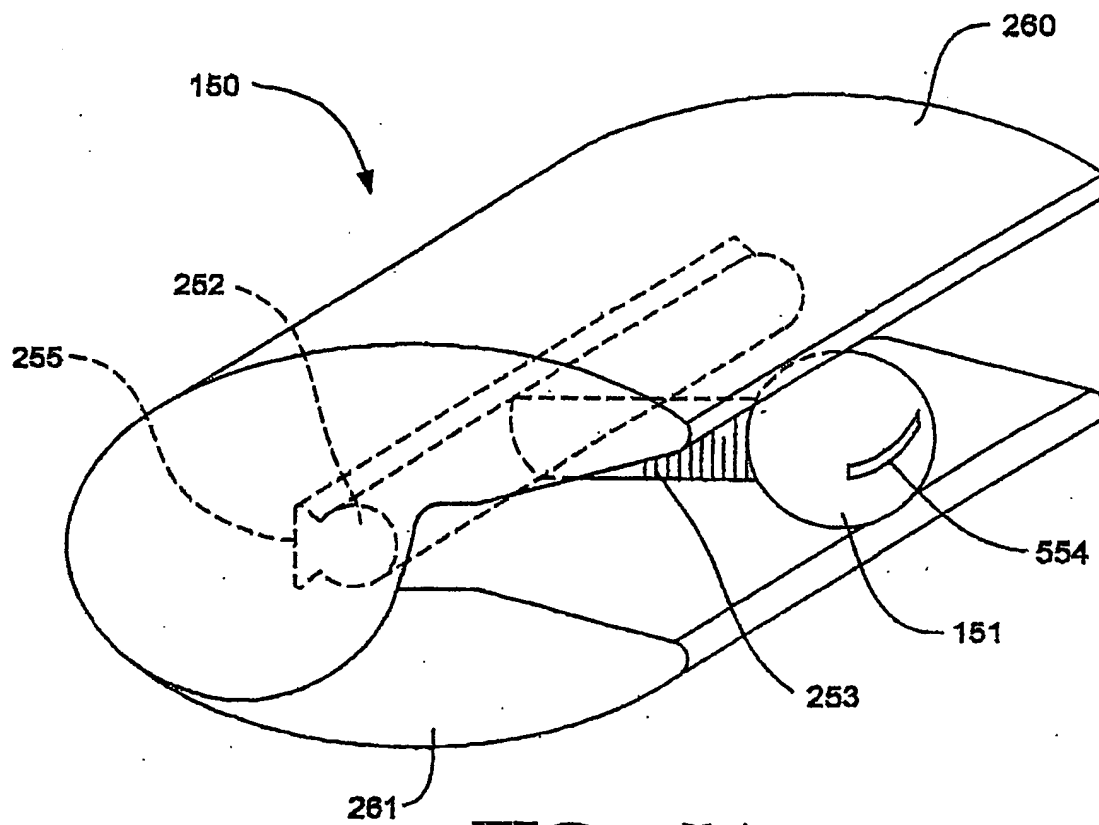


FIG. - 5A

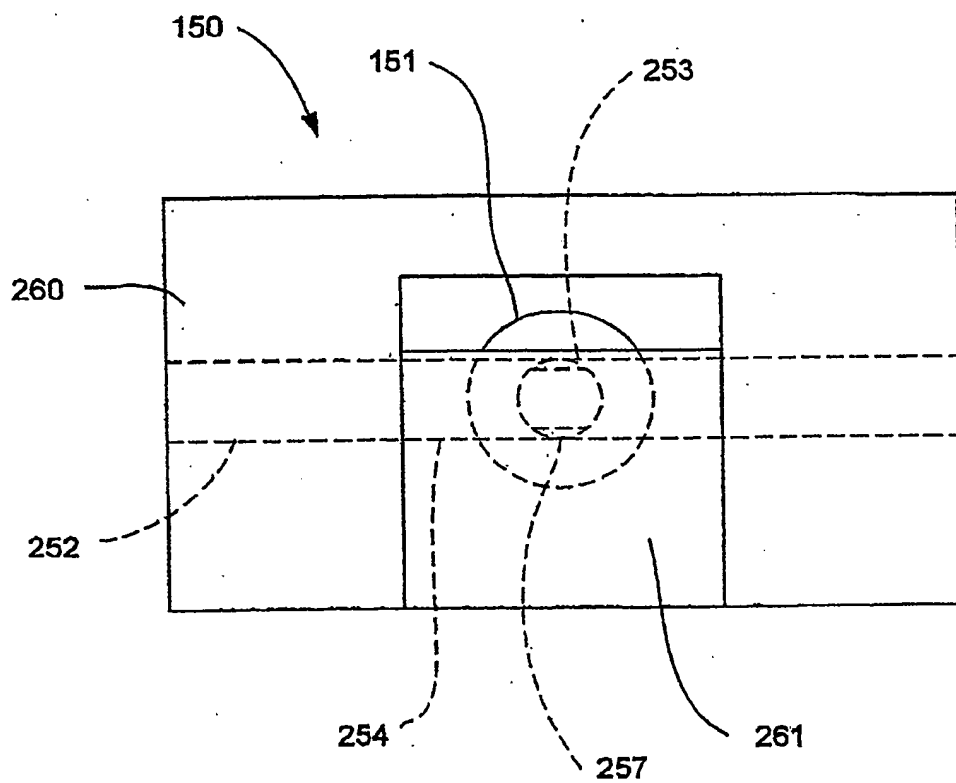


FIG. - 5B

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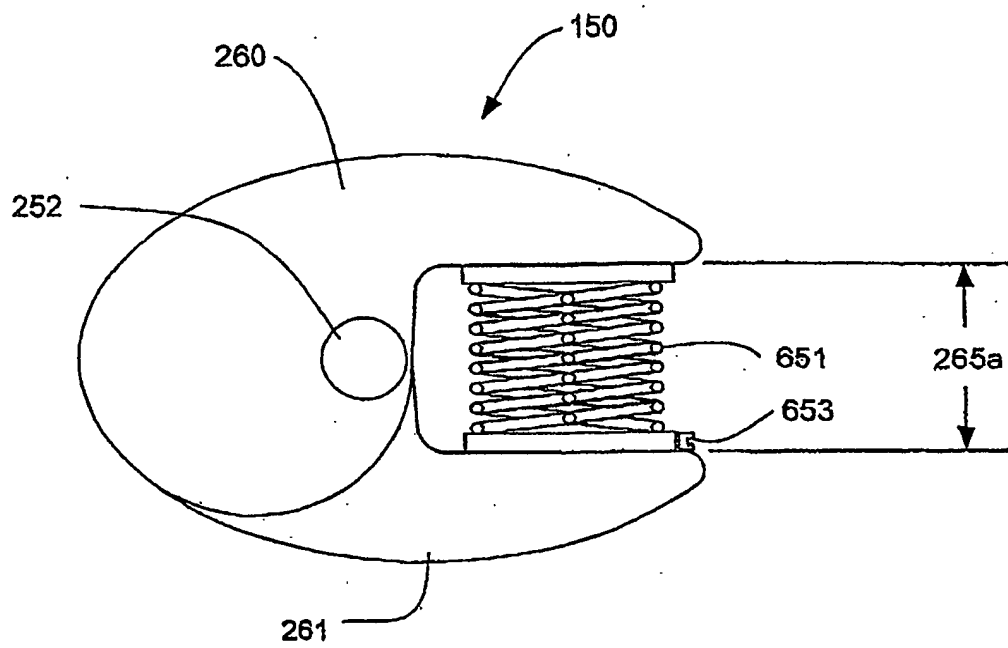


FIG. - 6A

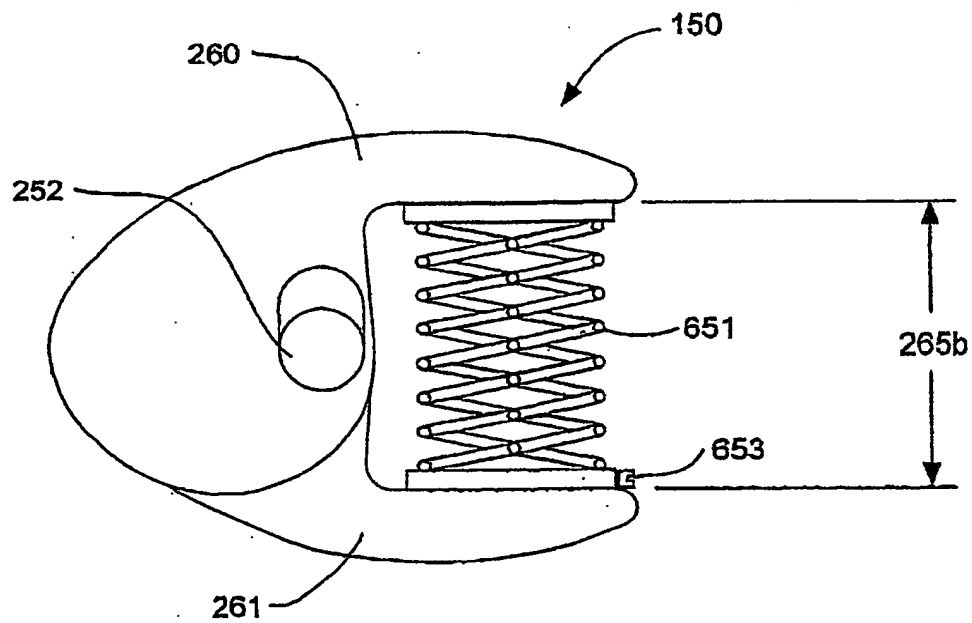


FIG. - 6B

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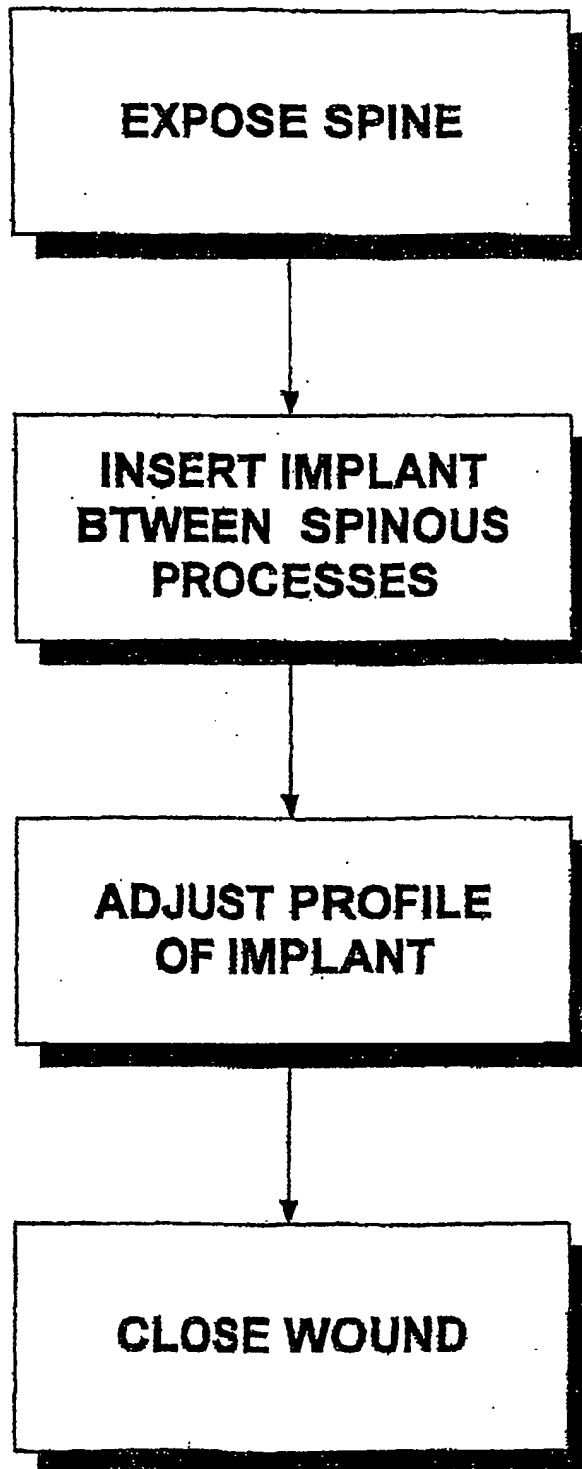


FIG. - 7